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Practical implementation of the PIC/S principles in Ukraine after its accepting international requirements for quality control of medicinal products

Pharmaceutical Inspection Cooperation Scheme (PIC/S) is an international instrument of interaction between countries and regulatory authorities in the sphere of quality control of medicines (by national pharmaceutical inspectorates), which together provide an active and constructive cooperation in the field of good manufacturing practices (GMP), inspection and licensing.

Aim. To develop a strategy, tactics and sequence of applying adaptation mechanisms to the pharmaceutical industry legislation of Ukraine according to EU and the PIC/S requirements.

Results. In 2010, within Ukraine joining to the PIC/S the starting audit of researches on adaptation of medicinal products quality standards to the international requirements was carried out. In the period from March 22 to 26, 2010 the PIC/S audit team performed the final audit in order to check the readiness of Ukraine to join the PIC/S. On November 8, 2010 a decision on Ukraine's membership was made in Kuala Lumpur (Malaysia). Since January1, 2011 Ukraine has become the PIC/S member within the system of medicinal products circulation and quality control in accordance with GMP/GDP and EU Directive 2001/83/EC. During the period of Ukraine's accession to the PIC/S system, accordingly, this Directive was improved. At the VIII National pharmaceutical Congress (Kharkiv, September 14-16, 2016) 26 additions to the decision of Congress were proposed, including questions related to the PIC/S and other legislative initiatives.

Conclusions. Legislative documents of the system of medicines quality control and circulation inspection are the international requirements of the PIC/S. The principles, measures and requirements were developed, discussed and accepted that contributed to the accession of Ukraine to the PIC/S system in 2011.

Key words: quality of medicines; pharmacy; the national and foreign legislation in the sphere of medicine circulation

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Практична реалізація принципів PIC/S у процесі приєднання України до міжнародних вимог системи контролю якості лікарських засобів

Міжнародна система співробітництва фармацевтичних інспекцій (Pharmaceutical Inspection Cooperation Scheme, PIC/S) – це міжнародний інструмент взаємодії між країнами та регуляторними органами у сфері контролю якості лікарських засобів (національними фармацевтичними інспекторатами), які забезпечують разом активну та конструктивну співпрацю у сфері Належної виробничої практики (Good Manufacturing Practice, GMP), інспектування та ліцензування.

Метою роботи була розробка стратегії, тактики та послідовності застосування механізмів адаптації національного фармацевтичного законодавства України відповідно до вимог ЄС та PIC/S.

Результати. Дослідження з адаптації норм системи якості лікарських засобів у рамках вступу України до PIC/S у 2010 році пройшли відповідний стартовий аудит. У період з 22 по 26 березня 2010 року Аудиторською групою PIC/S проведено аудит готовності України до завершального етапу процедури вступу до PIC/S. 8 листопада 2010 р. у м. Куала-Лумпур (Малайзія) було прийняте рішення про приєднання України до членів PIC/S у 2011 році у сфері системи обігу та контролю якості лікарських засобів відповідно до вимог GMP/GDP та Директиви 2001/83/ЕС. За період приєднання України до системи PIC/S, відповідно, відбулися деякі вдосконалення цієї Директиви. На VIII Національному фармацевтичному з'їзді (Харків, 14-16 вересня 2016 р.) запропоновано 26 доповнень до рішення з'їзду, зокрема з питань PIC/S та інших законодавчих ініціатив.

Висновки. Нормативно-правова база системи контролю якості лікарських засобів та контролювання їх обігу є міжнародною вимогою PIC/S. Розроблені, обговорені та впроваджені прин-

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ципи, заходи та вимоги PIC/S, за допомогою чого було зроблено значний внесок у приєднання України до PIC/S у 2011 році.

Ключові слова: якість лікарських засобів; фармація; національне та іноземне законодавство у сфері обігу лікарських засобів

А. С. Соловьев

Практическая реализация принципов PIC/S в процессе присоединения Украины к международным требованиям системы контроля качества лекарственных средств

Международная система сотрудничества фармацевтических инспекций (Pharmaceutical Inspection Cooperation Scheme, PIC/S) – это международный инструмент взаимодействия между странами и регуляторными органами в сфере контроля качества лекарственных средств (национальными фармацевтическими инспекторатами), которые обеспечивают вместе активное и конструктивное сотрудничество в сфере надлежащей производственной практики (Good Manufacturing Practice, GMP), инспектирования и лицензирования.

Целью работы является разработка стратегии, тактики и последовательности применения механизмов адаптации национального фармацевтического законодательства Украины согласно требованиям ЕС и PIC/S.

Результаты. Исследования по адаптации норм системы качества лекарственных средств в рамках вступления Украины в PIC/S в 2010 году прошли соответствующий стартовый аудит. В период с 22 по 26 марта 2010 года Аудиторской группой PIC/S проведено аудит готовности Украины к заключительному этапу процедуры вступления в PIC/S. 8 ноября 2010 г. в г. Куала-Лумпур (Малайзия) было принято решение о присоединении Украины к членам PIC/S с 1 января 2011 года в сфере системы оборота и контроля качества лекарственных средств согласно требованиям GMP/GDP и Директивы 2001/83/ЕС. За период присоединения Украины к системе PIC/S, соответственно, произошли некоторые усовершенствования этой Директивы. На VIII Национальном фармацевтическом съезде (Харьков, 14-16 сентября 2016 г.) предложено 26 дополнений к решению съезда, в т. ч. по вопросам PIC/S и других законодательных инициатив.

Выводы. Нормативно-правовая база системы контроля качества лекарственных средств и контроля их оборота является международным требованием PIC/S. Разработаны, обсуждены и внедрены принципы, мероприятия и требования PIC/S, благодаря чему осуществлен значительный вклад в присоединение Украины к системе PIC/S.

Ключевые слова: качество лекарственных средств; фармация; национальное и зарубежное законодательство в сфере оборота лекарственных средств

STATEMENT OF THE PROBLEM

The increased number of medicines in the pharmaceutical market of Ukraine increases and declaring the requirements for their quality control. This is confirmed by numerous studies both domestic and foreign authors [2, 5, 6, 10, 14, 20]. Special standard-legislative documents regulating the international legal practice: Guidelines, Directives and other factors of EU.

ANALYSIS OF RECENT RESEARCHES AND PUBLICATIONS

Legislative activity in health care, pharmacy finds permanently-stream realization. As stated, 21 of November 2016 in the Committee of the Parliament of Ukraine regarding the health care, there was a meeting of healthcare professionals, pharmacy and scientists behind "the round table" on the theme: "Legislative initiatives of the new national health care system". Among the priority list of laws was included the Law of Ukraine "On Medicinal Products" in the new edition.

Adaptation of the basic legislation documents in the sphere of circulation of medicines, their quality control, promotion, advertisement to EU requirements in the draft law of Ukraine organizes the activity in the field of pharmacy, minimizes the negative events in the falsification of drugs, contributes to availability of high-quality, effective and safe medicines for the population of Ukraine.

IDENTIFICATION OF ASPECTS OF THE PROBLEM UNSOLVED PREVIOUSLY

Pharmaceutical Inspection Cooperation Scheme (PIC/S) is an international instrument of interaction between countries and regulatory authorities in the sphere of quality control of medicines (by national pharmaceutical inspectorates), which together provide an active and constructive cooperation in the field of Good Manufacturing Practices (GMP), inspection and licensing [20]. Such organizations, as The World Health Organization (WHO), UNICEF, and Global Fund to Fight AIDS, Tuberculosis and Malaria acknowledge the compli-

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ance with quality standards of medicines, if manufacturers have passed inspection by the competent authorities, which are members of PIC/S [7-9]. The main objectives and benefits of membership PIC/S established: strengthening of cooperation between the competent authorities in the area of inspections and the promotion of their quality; exchange of information and experience between the competent authorities; improvement and harmonization of standards and procedures for inspections of manufacturers of drugs and control of medicines in authorized laboratories; promotion of harmonization of GMP/GDP requirements; expanding of cooperation between competent authorities through the use of equivalent standards and procedures; coordination of training and periodic training of inspectors; mutual recognition of conformity certificates of medicines manufacturing with the GMP/GDP requirements [1, 3, 4, 16-19, 21-26].

When determining the competency of the competent authority in the sphere of control over the circulation of medicines to PIC/S included a detailed assessment, which is performed in order to determine, whether the appropriate authority has responsibilities and competence, which are necessary for the application of the control system, equivalent to the national systems of the state competent authority in the sphere of control over the circulation of medicines, which are members of PIC/S. This assessment involves verification of the system of Inspectorate of the Good Manufacturing Practice (GMP) by the national empowered competent effect, regarding procedures of inspection and licensing, implemented system of quality, national requirements, training of inspectors, etc. [10-15].

Based on this we made some additions, changes, proposes, which in our opinion should be taken into account when presenting for the consideration of the Parliament of Ukraine the Ukrainian Law "On Medicinal Products" in the new edition. Almost simultaneously, we have made 26 supplements to the decision of VIII National Congress of Pharmacists of Ukraine (On 14-16 of September 2016). According to some sections of the decision of the VIII congress of pharmacists concerns the legislative and normative regulation regarding: the concept of pharmaceutical sector of Healthcare of Ukraine development on 2016-2021; production of medicines in Ukraine: Realities and Perspectives; the pricing, reimbursement, as factors of availability of medicines; the concept and standards of higher education in Ukraine in the field of knowledge: "Health Care" in specialty "Pharmacy" and "Higher Education"; integration of pharmacy of Ukraine in European pharmaceutical space; improvement of regulatory policy in the pharmaceutical sector; pharmaceutical self-government; development tendencies of pharmacy network, distribution, quality control; pharmaceutical science and innovative technologies in the development of medicines. The mentioned problems coincide with the questions, which were asked behind the "round table" of the Committee of the Parliament on 21.11.2016.

OBJECTIVE STATEMENT OF THE ARTICLE

Taking into account actuality of legislative activity, with the aim of implementation of national pharmaceutical law to the requirements of EU and efficiency of certainty in the innovative problematic set the goal – develop a strategy and tactics and sequence of development adaptation mechanisms of normative base in the pharmaceutical industry of Ukraine according to EU and PIC/S requirements.

At that stage, we together with national authorized competent authority processed application to PIC/S and a package of scientific practical and reasonable instruments for it [10-15]. Event of forming research purposes regarding joining the PIC/S anticipated the following not resolved earlier parts of the abovementioned problem: the appointment at the PIC/S Committee meeting of curator of the Evaluation of statement; checking the licensing system and inspection of activities for the production and distribution of medicines, the Inspectorate of the quality system, national legal requirements, procedure of training and preparation of inspectors, etc.; visit with the purpose of audit for the audit team PIC/S, carrying out the observations over the work of inspectors, which performing routine inspections for compliance with the GMP/PIC/S requirements; the adoption at the PIC/S Committee meeting of according to the evaluation results of the audit team PIC/S final decision concerning the accession of the national competent authority in the sphere of the control by the circulation of medicines to the PIC/S.

PRESENTATION OF THE MAIN MATERIAL FOR THE RESEARCH

The successive stages and the final steps of accession to the PIC/S were argued according to the recommendations, which were specified at the PIC/S seminar for inspectors in Bratislava. To the PIC/S management were prepared and passed the official justification about the intentions of Ukraine to join this organization and to develop and justify the implementation of admission procedures to the PIC/S. It is emphasized, that at the initial, the starting point the accession procedure was started with the evaluation of the application and added documents and justified and effective supervision over inspection and assessment of functioning of the quality system of inspectorate. On the next step was formulated resume (CV) of inspectors, the system of their training and ongoing learning and required the development of a number of standard operating pro-

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cedures (SOP) etc. We, together with National Pharmaceutical University (academy) and other universities of Ukraine, international experts-consultants was developed a scheme – algorithm scientific-design entry and implementation of quality control system of medicines in the international system of PIC/S.

As a result of this work, in 2004 has been filed an official statement. On the 1 of November in the same year were prepared, justified and transferred all necessary official documents, which should be added to the statement. The curators of the accession of the national authorized competent authority of Ukraine to the PIC/S were identified official representatives of the authorized competent authority of Ireland and Slovakia, followed by the beginning of the accession process. As at the initial stage of the accession of Ukraine to the PIC/S, as well as on the other organizational legal stages were marked some conflicts with developers, regarding a complete continuation of the procedure of accession to the PIC/S, namely: the discrepancy of licensing procedures of manufacturers of medicinal products and their certification for compliance with GMP were not included as mandatory for license conditions of carrying economic activity on industrial production of medicines. For recovery of aforementioned statement, were submitted all necessary documents and accepted events of active implementation of set of regulatory factors of Ukraine adapted to the requirements of EU, taking into account the following: quality manual, resume (CV) on each inspector, the description of quality assessment system of inspection, the necessary standard operating procedures of inspectorate, etc. [9, 10, 13, 15, 21].

On the basis of audit was established scientific-practice and controlling activity, which was carried out from 2 of 3 technical-structural sector-departments, that were part of public administration, regarding the regulation of drug production according to the functional-organizational-control features, namely: Department of organization of state control quality of medicines, who has control over the export and import of medicines, certification of laboratories, the prohibition (termination) and removal from circulation of medicines; Division on licensing and certification of manufacturing, which was responsible for licensing and inspection of manufacturers of medicinal products [9, 14, 21-26].

By the PIC/S representatives was noted the significant progress of developed and proposed efficiency of the quality system of Ukraine and the current legislative process in the Law in accordance with the PIC/S requirements in the sphere of circulation of medicines. During the final meeting of the PIC/S we have taken into account the following:

- First of all, the expressed satisfaction of members-experts of PIC/S to the scientists, practical experts, State Inspectorate for Quality Control of Medicines and the Ministry of Health of Ukraine for the organization of work regarding the preparation of the practical background for adaptation of the list of laws of Ukraine which are adapted and interconnected to the legislative and regulatory framework to the integral international requirements of the system PIC/S in Ukraine;
- Difficulty of the audit;
- The productivity of researchers activity and complicity of public authorities, which was demonstrated on the final stage of implementation and entry of Ukraine as 37 member of the PIC/S system;
- Recognized validation of processes at all production stages of the relevant principles of quality control system of medicines, according to the PIC/S system;
- Qualified selection of scientific, practical workers and also skilled learning, training of advanced inspectors and their improvement;
- Preparation and implementation of these stages of the evaluation process of accession to the PIC/S.

The results of researches, passing the stages of joining the PIC/S and final analytical material of audit was indicated also some propositions regarding the further activity of regulatory authorities in Ukraine according to the PIC/S requirements [13]. The first critical component, which needed substantial revision, concerned the legal requirements, regarding: pharmaceutical companies, who import medicines, did not have license for the manufacture and/or import of medicines. Differences were detected concerning import of medicines, procedure for cancellation of the manufacturer license and certificate of conformity to the GMP requirement. It is established that importers of medicines in Ukraine which do not have any license on production or appropriate permission which would include product quality review and GMP standards during the production of imported goods considered acceptable. We, together with the central administrative-supervisory authorities, Universities provided generalized scientific-practical reasoned explanation regarding this matter. It has been proved that according to the current legislation pharmaceutical companies, who import medicines, should have had a license for wholesale trade. Control of circulation of imported medicines, before introduction of changes of abovementioned amendments to the regulatory framework was implemented in several steps on the territory of Ukraine: control of the distribution company by authorized specialists (A Qualified person of quality); state control at all stages of circulation of imported medicines by the State Inspectorate for Quality Control of Medicines (State Administration of Ukraine on Medicinal Products, SAUMP) and its territorial inspections in accor-

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dance with current legislation of Ukraine. The second critical component that needed our revision, concerned the GMP standards, namely: Ukrainian text of GMP requirements was not actualized with the current version of GMP EU, which was absent at that time, a respective standard operating procedure regarding the control of changes according to GMP EU and actualization of the text of national GMP requirements (Ukrainian language). To eliminate this remark, as already mentioned was scheduled the actualization of the Guideline STN MHU 42-4.0:2008 "Medicinal Products. Good manufacturing practice" in accordance with applicable requirements of GMP EU and development of SOP regarding its actualization on the on a regular basis in accordance with changes, which is made in GMP EU. Other discrepancies related the appointment, training and education of inspectors, inspection procedures and methodologies, sampling plan etc. General final form our research areas of joining to PIC/S together with scientists of National University of Pharmacy and other medical Universities and the State Inspectorate for Quality Control of Medicines successfully confirmed the a complete value of Ukraine in the PIC/S system.

Based on the aforementioned at the next PIC/S meeting of, which took place on 8 of November 2010 in the Kuala Lumpur (Malaysia), it was decided to join Ukraine to the PIC/S members started from 1 of January 2011.

CONCLUSIONS AND PROSPECTS FOR FURTHER RESEARCH

Legislative document of drug quality control system and processes of control inspection (PIC/S) in the sphere of their circulation – is international requirements of PIC/S. Developed, discussed and accepted the principles, measures and requirements to PIC/S in Ukraine and contributed the accession of Ukraine in 2011 to the PIC/S system.

Conflicts of Interest: authors have no conflict of interest to declare.

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